K060651

510(K) SUMMARY

SEP 13 2006

1.1. ADMINISTRATIVE INFORMATION

Name:	St. Jude Medical
Address:	6550 Wedgwood Road North
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	Maple Grove, MN 55311
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Contact Person:	Kimberly Briggs
	Senior Regulatory Affairs Specialist
Date:	March 10, 2006

1.2. PROXIS SYSTEM DEVICE INFORMATION

Name of Device:	Proxis System
Common Name:	Proximal Embolic Protection Device
Classification Name:	Device, coronary saphenous vein bypass graft, temporary, for embolization protection (870.1250)
Device Classification:	Class II
Product Code:	NFA

1.2.1. PREDICATE DEVICE INFORMATION

The Proxis System included in this 510k submission is a modification to the current Proxis System by implementing three primary design changes and an expansion of indications to allow for use as an embolic protection system.

This Proxis System is physically identical to the predicate Proxis System, which is market cleared for a Flow Control indication (K042117) with the exception of three primary design modifications. The three primary changes include: Proxis catheter type changed from 'rapid-exchange' type to an 'over-the-wire' type., inflation device change from syringe type w/saline to pushbutton type w/CO2 and the backend configuration changed from a double Y-adaptor to a single Y-adaptor. The Proxis System is similar in function and intended use to market cleared predicate embolic protection systems: the FilterWire (K023691), GuardWire Temporary Occlusion and Aspiration System

(K023878) and TriActiv (K042040).

1.2.2. DEVICE DESCRIPTION

The Proxis System is a proximal embolic protection system used in conjunction with other interventional devices. The Proxis System protects the patient from distal embolization by preventing antegrade flow of emboli release during an interventional procedure and then removing it from the vessel. The Proxis System consists of an Evacuation Sheath Catheter compatible with 7F or larger guide catheters, Inflation device, Aspiration syringe, Lip Seal and Strainer basket. In addition, an optional accessory called the Proxis Infusion Catheter (packaged separately, K023548) may be used with Proxis System.

The Proxis catheter is loaded onto the guide wire and tracked down to the distal portion of the guide catheter and proximal to the lesion site. To minimize the occlusion time, the interventional devices are advanced through the Proxis catheter and positioned near the distal tip. When the sealing balloon is inflated, antegrade flow of the fluid in the target vessel is prevented. To minimize the release of embolic material, stagnation of flow is accomplished before any devices touch or cross- the lesion(s).

In the stagnant flow, the guide wire is advanced across the lesion site and the interventional device is tracked over the guide wire. After the treatment, fluid and particles from the procedure are evacuated using the aspiration syringe. If there is insufficient venous or collateral flow, the Proxis Infusion Catheter (optional accessory) may be used to deliver saline distal to the treatment site while simultaneously applying vacuum to evacuate fluid and particles from the treatment site.

1.2.3. INTENDED USE

The Proxis System is indicated for use as a proximal embolic protection system to prevent distal release of and to aspirate embolic material (thrombus/debris) in saphenous vein coronary bypass graft(s) (3.0 mm – 5.0 mm) during percutaneous transluminal coronary angioplasty and/or stenting procedures.

The Proxis System is also indicated to control the flow of fluids in the coronary and peripheral vasculature.

The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral, carotid or peripheral vasculature; native coronary arteries; or for treatment of patients with acute myocardial infarction.

1.2.4. TECHNOLOGICAL CHARACTERISTICS

The Proxis device is physically the same Proxis device that was cleared under the flow-control indication (K042117) with the exception of three primary design modifications. The three primary changes include: Proxis catheter type ('over-the-wire' vs. 'rapid-exchange'), inflation device (pushbutton type w/CO2 vs. syringe type w/saline) and the backend configuration (single Y-adaptor vs. double Y-adaptor). The other difference is an expansion of the indications for embolic protection. The embolic protection expansion is supported by clinical data from the Proximal Trial that demonstrates substantial equivalence to previously cleared predicate devices that have similar indications, i.e. FilterWire EX Embolic Protection System (K023691) and PercuSurge GuardWire Temporary Occlusion and Aspiration System (K013913) and the Kensey Nash TriActiv (K042040). The primary difference in technologies to the predicate devices is that the Proxis System provides proximal occlusion vs. distal occlusion.

1.3. SUMMARY OF NON-CLINICAL TESTING

Non-clinical verification and validation of the Proxis System was performed through extensive in vitro bench testing, biocompatibility testing, and sterilization, shelf life testing and *in vivo* animal studies. Results of the testing demonstrated that the Proxis System design met all specifications and intended uses.

1.4. SUMMARY OF CLINICAL DATA

The modifications to the Proxis System do not impact the therapeutic aspect of the Proxis Embolic Protection System. As such, a physician evaluation (20 patients) was performed to evaluate the usability aspects of the modified Proxis System as compared to the current Proxis System. In addition, the Proximal Trial was performed to assess the safety and effectiveness of the current Proxis System for embolic protection during percutaneous treatment of saphenous vein graft (SVG) stenosis. The study consisted of a test arm (Proxis Embolic Protection System + current practice) and a control arm (current practice with market cleared distal protection devices, FilterWire and GuardWire). Six-hundred (600) randomized patients, with 117 additional roll-in and 5 educational patients were enrolled in 68 investigational sites in Canada, Europe and the United States. Five-hundred ninety-four (594) randomized patients were included in the analysis. The following conclusions resulted from the study:

Table 1: Proximal Trial Results

Patient Group	MACE		Confidence Intervals
Intent to treat (as randomized)	Test (n=294)	9.2%	Diff -0.8 CI [-5.5%, 4.0%]
	Control (n=300)	10.0%	P=0.006 for non-inferiority
Per Protocol (patients who received the assigned device)	Proxis (n=240)	7.1%	Diff -3.1 CI [-8.1%, 2.0%]
	Distal (n=236)	10.2%	P=0.001 for non-inferiority
As treated (patients analyzed based on treatment received)	Proxis (n=241)	7.1%	Diff -4.6 CI [-9.6%, 0.3%]
	Distal (n=282)	11.7%	P<0.001 for non-inferiority
	No Protection (n=70)	10.0%	
Mid-Portion (patients who could be treated with either device)	Proxis (n=177)	6.2%	Diff -5.0 CI [-10.6%, 0.6%]
	Distal (n=205)	11.2%	P=0.0001 for non-inferiority

1.5 CONCLUSION

In conclusion, the Proxis System included in this submission is substantially equivalent to the existing Proxis System (K042117), FilterWire Embolic Protection System (K023691), Guardwire Temporary Occlusion and Aspiration System (K023878), and TriActiv (K042040).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 13 2006

Ms. Kimberly Briggs
Senior Regulatory Affairs Specialist
St. Jude Medical
6550 Wedgwood Road North, Suite 150
Minneapolis, MN 55311

Re: K060651
Trade/Device Name: Proxis System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NFA
Dated: September 8, 2006
Received: September 11, 2006

Dear Ms. Briggs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Lochner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060651

Device Name: Proxis System

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K060651